

Exhibit 20

Document produced natively
TEVA-MDL2875-00001350

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

pdr-ele-impu-risk.pdf

ANDA\091519 Submissions\Submissions\CTD\091519\0042\m3\32-body-data\32p-drug-
prod\valsartan-and-hydrochlorothiazide-tablets-all-strengths\32p2-pharm-dev\

4202596B0BEE4761C41A1ECAFA898190



**QUALITY RISK ASSESSMENT
OF ELEMENTAL IMPURITIES IN THE FINISHED DOSAGE FORM FOR
VALSARTAN HYDROCHLOROTHIAZIDE TABLETS.**


Arrow Pharm (Malta) Ltd.

Title: Quality Risk Assessment of Elemental Impurities in the
finished dosage form for Valsartan Hydrochlorothiazide
Tablets.

RISK ASSESSMENT STUDY (RM-079)

*Quality Risk Assessment of Elemental Impurities (ICH Q 3D) in
the finished dosage form for Valsartan Hydrochlorothiazide
Tablets.*

3.2.P.2 ELEMENTAL IMPURITIES INITIAL RISK ASSESSMENT REPORT

	Valsartan Hydrochlorothiazide Tablets, 80/12.5mg, 160/12.5mg, 160/25mg, 320/12.5mg and 320/25mg
	Risk Assessment Report: RM-079

Prepared By: [REDACTED]
[REDACTED]
Senior Quality Control Analyst

Date: 25 July 17

Reviewed: [REDACTED]
[REDACTED]
Quality Control Supervisor

Date: 25th July 2017

Approved: [REDACTED]
[REDACTED]
Quality Systems Manager

Date: 27 JUL 2017

Approved: [REDACTED]
[REDACTED]
Production and Process
Validation Manager

Date: 2 Aug - 2017

Approved: [REDACTED]
[REDACTED]
Quality Assurance Manager/QP

Date: 03 Aug 2017